

S/N 09/613,604
Confirmation No.: 1097

PATENT

In the Specification

The paragraph beginning on page 10, line 12 has been amended as follows:

--Another embodiment of the sensor may be used for *in vitro* measurement of a level of an analyte. The *in vitro* sensor is coupled to a control unit and/or a processing unit to form an analyte monitoring system. In some embodiments, an *in vitro* analyte monitoring system is also configured to provide a sample to the sensor. For example, the analyte monitoring system may be configured to draw a sample from, for example, a lanced wound using a wicking and/or capillary action. The sample may then be drawn into contact with the sensor. Examples of such sensors may be found in U.S. Patent Application Serial No. 08/795,767 (now abandoned, but continuations of which include U.S. Patent Nos. 6,143,164 and 6,120,676) and PCT Publication No. WO 98/35225 [Patent Application No. _____], entitled "Small Volume *in vitro* Analyte Sensor", [filed on February 6, 1998, Attorney Docket No. 12008.11WO01,] incorporated herein by reference.--

The paragraph beginning on page 16, line 17 has been amended as follows:

--The conductive traces 52 may be formed on the substrate 50 by a variety of techniques, including, for example, photolithography, screen printing, or other impact or non-impact printing techniques. The conductive traces 52 may also be formed by carbonizing conductive traces 52 in an organic (e.g., polymeric or plastic) substrate 50 using a laser. A description of some exemplary methods for forming the sensor 42 is provided in U.S. Patent [Application Serial] No. 6,103,033 [_____, entitled "Process for the Manufacture of an Electrochemical Biosensor", filed on March 4, 1998, Attorney Docket No. M&G 12008.16US01], incorporated herein by reference.--

S/N 09/613,604

PATENT

Confirmation No.: 1097

The paragraph beginning on page 16, line 25 and extending to page has been amended as follows:

--Another method for disposing the conductive traces 52 on the substrate 50 includes the formation of recessed channels 54 in one or more surfaces of the substrate 50 and the subsequent filling of these recessed channels 54 with a conductive material 56, as shown in Figure 3A. The recessed channels 54 may be formed by indenting, embossing, or otherwise creating a depression in the surface of the substrate 50. Exemplary methods for forming channels and electrodes in a surface of a substrate can be found in U.S. Patent [Application Serial] No. 6,103,033 [_____], entitled "Process for the Manufacture of an Electrochemical Biosensor", filed on March 4, 1998, Attorney Docket No. 12008.16US01]. The depth of the channels is typically related to the thickness of the substrate 50. In one embodiment, the channels have depths in the range of about 12.5 to 75 μm (0.5 to 3 mils), and preferably about 25 to 50 μm (1 to 2 mils).--

The paragraph beginning on page 26, line 15 has been amended as follows:

--The sensing layer 64 may be formed as a solid composition of the desired components (e.g., an electron transfer agent and/or a catalyst). These components are preferably non-leachable from the sensor 42 and more preferably are immobilized on the sensor 42. For example, the components may be immobilized on a working electrode 58. Alternatively, the components of the sensing layer 64 may be immobilized within or between one or more membranes or films disposed over the working electrode 58 or the components may be immobilized in a polymeric or sol-gel matrix. Examples of immobilized sensing layers are described in U.S. Patents Nos. 5,262,035, 5,264,104, 5,264,105, 5,320,725, 5,593,852, and 5,665,222, and PCT Publication No. WO 98/35053 [U.S. Patent Application No. 08/540,789, and PCT Patent Application No. _____] entitled "Soybean Peroxidase Electrochemical Sensor", filed on February 11, 1998, Attorney Docket No. M&G 12008.8WOI2], incorporated herein by reference.--

S/N 09/613,604

PATENT

Confirmation No.: 1097

The paragraph beginning on page 28, line 27 and extending to page 29 has been amended as follows:

--For example, a glucose or lactate sensor may include a first sensing layer 64 which is spaced apart from the working electrode and contains an enzyme, for example, glucose oxidase or lactate oxidase. The reaction of glucose or lactate in the presence of the appropriate enzyme forms hydrogen peroxide. A second sensing layer 63 is provided directly on the working electrode 58a and contains a peroxidase enzyme and an electron transfer agent to generate a signal at the electrode in response to the hydrogen peroxide. The level of hydrogen peroxide indicated by the sensor then correlates to the level of glucose or lactate. Another sensor which operates similarly can be made using a single sensing layer with both the glucose or lactate oxidase and the peroxidase being deposited in the single sensing layer. Examples of such sensors are described in U.S. Patent No. 5,593,852 and U.S. Patent No. 6,665,222, and PCT Publication No. WO 98/35053, [U.S. Patent Application No. 08/540,789, and PCT Patent Application No. _____ entitled "Soybean Peroxidase Electrochemical Sensor", filed on February 11, 1998, Attorney Docket No. M&G 12008.8WOI2,] incorporated herein by reference.--

The paragraph beginning on page 35, line 13 has been amended as follows:

--Another consideration for *in vivo* analyte sensors is the thermostability of the catalyst. Many enzymes have only limited stability at biological temperatures. Thus, it may be necessary to use large amounts of the catalyst and/or use a catalyst that is thermostable at the necessary temperature (e.g., 37°C or higher for normal body temperature). A thermostable catalyst may be defined as a catalyst which loses less than 5% of its activity when held at 37°C for at least one hour, preferably, at least one day, and more preferably at least three days. One example of a thermostable catalyst is soybean peroxidase. This particular thermostable catalyst may be used in a glucose or lactate sensor when combined either in the same or separate sensing layers with glucose or lactate oxidase or dehydrogenase. A further description of thermostable catalysts and

C

S/N 09/613,604

PATENT

Confirmation No.: 1097

their use in electrochemical inventions is found in U.S. Patent No. 5,665,222 and PCT

Publication No. WO 98/35053 [U.S. Patent Application No. 08/540,789, and PCT

Application No. _____ entitle "Soybean Peroxidase Electrochemical Sensor", filed on

February 11, 1998, Attorney Docket No. M&G 12008.8WOI2].--

C